

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2170631	<b>(X3) Date Survey Completed</b>  03/11/2020
<b>Name of Provider or Supplier</b>  Quest Md Clinics Minden	<b>Street Address, City, State</b>  10600 Industrial Dr, Minden, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An Initial Certification survey was performed at Quest MD Clinics Minden, CLIA ID # 19D2170631 on March 11, 2020. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director and Testing Personnel signed the attestation statement for one (1) of one (1) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's College of American Pathologists (CAP) proficiency testing records revealed the Laboratory Director and Testing Personnel did not sign the attestation statement for the following event: a) FH9-A 2020 Hematology Automated Differential Survey Event 1 2. In interview on March 11, 2020 at 01:20 pm, the facility representative stated that the missing signatures was an oversight. The facility representative confirmed the attestation statement was not signed for the above event.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that</p>

perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the laboratory failed to document corrective action performed when the room temperature was not maintained within acceptable range per laboratory policy. Findings: 1. Review of the laboratory's "Temperature/Humidity Monitoring" policy revealed under "Corrective Action" "Initiate and document appropriate corrective action when readings exceed the acceptable performance range. Documentation must include the date and description of the corrective action to include patient impact and the reading after corrective action was completed". 2. Review of the laboratory's "Min/Max Temperature Monitoring Log" revealed the room temperature acceptable range was documented as 18-25 degrees celsius. 3. Further review of the laboratory's "Min/Max Temperature Monitoring Log" for January 1, 2020 through March 11, 2020 revealed the room temperature was documented as outside of the acceptable limits without documented corrective actions for the following nine (9) days: a) January 15, 2020 documented room temperature 26 degrees celsius b) January 21, 2020 documented room temperature 26 degrees celsius c) February 3, 2020 documented room temperature 26 degrees celsius d) February 4, 2020 documented room temperature 28 degrees celsius e) February 5, 2020 documented room temperature 26 degrees celsius f) February 6, 2020 documented room temperature 26 degrees celsius g) February 7, 2020 documented room temperature 28 degrees celsius h) February 10, 2020 documented room temperature 26 degrees celsius i) March 11, 2020 documented room temperature 25 degrees celsius 3. In interview on March 11, 2020 at 01:45 pm, the facility representative confirmed that there was not any documentation of corrective action for the identified dates.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D2009.

**D6024**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(7)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.